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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,380	08/30/2001	S. Grant Mulholland	10303-2 US	7757

7590 12/02/2005

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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/943,380	<b>Applicant(s)</b> MULHOLLAND ET AL.	
	<b>Examiner</b> Ann Y. Lam	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-64 and 73-79 is/are pending in the application.
- 4a) Of the above claim(s) 65-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-64 and 73-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 12, 2005 has been entered.

### ***Double Patenting***

1. Claims 1-6, 8-21, 23,-25, 26-31, 32-48, 50-52, 53-60-64, and 73-79 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,464,670, in view of Sushko, 1,767,785.

Patent '670 teaches urethral suppository for delivery of therapeutic agents, the suppository comprising a member (16) that is ellipsoid and has a width that is greater than the width of the meltable portion. However, Patent '670 does not teach that an ellipsoid base member that is non-meltable, nor a non-meltable reinforcement. However, these elements are taught by Sushko.

Sushko teaches a non-meltable tube (10) with members (25) and (26), the members serving to provide compartments around the tube in which medicament is deposited and retained (see page 2, lines 16-24.) The tube (10) with members (25 and 26) are considered the claimed non-meltable reinforcement. Sushko also teaches a bulge (12, see fig. 2) which is non-meltable and is considered the base member. The bulge is to prevent undue removal of the device from the urethra (page 1, lines 65-70).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a tube and bulge taught by Sushko in Patent '670 because Sushko teaches that they provide the advantage of serving as a retaining member for the medicament and to retain the device in the body.

As to the following claims, Patent '670 teaches the limitations as follows.

As to claims 23 and 50, the medicament comprising antibiotics (col. 6, line 35.)

As to claim 32 and 58, the meltable portion is capable of melting within about 2 minutes to about 60 minutes.

As to claim 39, member (16) is capable of fitting within the labia minora of a patient.

As to claims 61 and 64, Patent '670 teaches that the ellipsoid member is not for insertion into the urethra (col. 9, lines 26-28.)

As to claims 76 and 79, Patent '670 teaches that a segment of the suppository remains in the urethra and another segment remains in the bladder (col. 9, lines 26-28).

As to claims 16, 17, 24, 25, 30, 31, 51, 52, 57, 59, 60 and 73-75, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering

the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In this case, Patent '670 teaches the general conditions of the claims, and discovering the dimensions as would be necessary to fit inside the body of patients is a discovery of optimum or workable ranges and thus involves only routine skill in the art under *In re Aller*.

As to claims 62, 63, 77 and 78, discovering the optimum or workable range of time for delivering medicine requires only routine skill in the art under *In re Aller*.

Also, as to claims 61 and 64, a method for delivering therapeutic agents to the female urinary tract using the suppository is disclosed (page 2, lines 83-93.)

As to the following dependent claims, Sushko teaches the limitations regarding the non-melttable elements as follows.

As to claims 2 and 34, the base member (12) is shaped for handling.

As to claims 8, 40, the base is comprised of polymer (page 1, lines 75-81.)

As to claim 9, the reinforcement is considered to be embedded within the base member. (Examiner notes that this claim is directed towards a device. Although the reinforcement and the base member may be integrally formed, at the proximal end, an inner and outer portion of the material can be considered the reinforcement and base member respectively.)

As to claims 10 and 41, the reinforcement (10) projects substantially perpendicular from said base member (see fig 3).

As to claims 11 and 42, the reinforcement (10) comprises a rod.

As to claims 12 and 43, the reinforcement is in the shape of a lattice (see 25 and 26 in fig. 7, and page 2, lines 16-24.)

As to claim 15, the second end of the reinforcement (10) extends outside the meltable portion. (The second end is considered to be a distal portion of 14 and 15, and the base member is considered to be the proximal portion of 14 and 15).

As to claims 13 and 44, the reinforcement (10) is formed from rubber (page 1, lines 74-77.)

As to claim 14, the second end of the reinforcement (44) is contained entirely within the meltable portion (medicine). (Examiner notes that Applicant has not defined where the "second end" starts, and thus Examiner interprets the "second end" in claim 14 to the distal end that is entirely covered with medicament.)

As to claims 18-21, 45-48, the reinforcement (10) comprises a restraint.

As to claims 26, 28, 29, 53, 55 and 56, Sushko discloses helical grooves (11) to retain the suppository inside the urethra (column 2, lines 5, and 54-56.)

As to claims 27 and 54, grooves (26) are parallel to the longitudinal axis of the meltable portion.

As to claims 5, 6, 37 and 38, the base member is at (18 and 11') and are grooved (see fig. 6).

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2. Claim 22 and 49 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,464,670, as applied to claims 1 and 33, in view of Jackson et al., 4,542,020.

Patent '670 in view of Sushko disclose the invention substantially as claimed (see above), except for the meltable portion comprising cellulose.

Jackson also teaches a suppository that melts for delivery of medication (column 62-65.) The suppository melts when placed in the patient (column 3, lines 24-28.) Jackson further teaches that the suppository comprises cellulose (column 3, lines 5-10) in order to provide for uniform distribution of the medication (col. 2, lines 6-12.)

It would have been obvious to provide cellulose in the meltable portion of the suppository as taught by Patent '670 in view of Sushko in order to provide the advantage of uniform distribution of medication as taught by Jackson.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-6, 8-15, 18-21, 26-29, 32-48, 53-56, 58, 61 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Sushko, 1,767,785.

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As to claims 1 and 33, Sushko teaches a non-meltable base member (13 and 14), and a non-meltable reinforcement (10), and a meltable portion (15) formed around the reinforcement, wherein the base member has a width greater than the width of the meltable portion (see fig. 3.)

As to claims 2 and 34, the base member (13 and 14) is shaped for handling.

As to claims 8, 40, the base is comprised of polymer (page 1, lines 75-81.)

As to claim 9, the reinforcement is considered to be embedded within the base member. (Examiner notes that this claim is directed towards a device. Although the reinforcement and the base member may be integrally formed, at the proximal end, an inner and outer portion of the material can be considered the reinforcement and base member respectively.)

As to claims 10 and 41, the reinforcement (10) projects substantially perpendicular from said base member (see fig 3).

As to claims 11 and 42, the reinforcement (10) comprises a rod.

As to claims 12 and 43, the reinforcement is in the shape of a lattice (see 25 and 26 in fig. 7, and page 2, lines 16-24.)

As to claim 15, the second end of the reinforcement (10) extends outside the meltable portion. (The second end is considered to be a distal portion of 14 and 15, and the base member is considered to be the proximal portion of 14 and 15).

As to claims 13 and 44, the reinforcement (10) is formed from rubber (page 1, lines 74-77.)



As to claim 14, the second end of the reinforcement (44) is contained entirely within the meltable portion (medicine). (Examiner notes that Applicant has not defined where the "second end" starts, and thus Examiner interprets the "second end" in claim 14 to the distal end that is entirely covered with medicament.)

As to claims 18-21, 45-48, the reinforcement (10) comprises a restraint.

As to claims 26, 28, 29, 53, 55 and 56, Sushko discloses a urethral suppository. Sushko further discloses helical grooves (11) to retain the suppository inside the urethra (column 2, lines 5, and 54-56.)

As to claims 27 and 54, grooves (26) are parallel to the longitudinal axis of the meltable portion.

As to claim 32 and 58, the meltable portion is capable of melting within about 2 minutes to about 60 minutes.

As to claim 39, the base member is capable of fitting within the labia minora of a patient.

Also, as to claims 61 and 64, a method for delivering therapeutic agents to the female urinary tract using the suppository is disclosed (page 2, lines 83-93.)

As to claim 3, 4, 35 and 36, the base member is considered to be at (12, see fig. 2) which is non-meltable and is considered the base member. The bulge is ellipsoid.

As to claims 5, 6, 37 and 38, the base member is considered to be at (11') and they are grooved (see fig. 6). (The reinforcement is at 18).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 16, 17, 24, 25, 30, 31, 51, 52, 57, 59, 60, 62, 63, and 73-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sushko, 1,767,785.

Sushko discloses the invention substantially as claimed (see above). More specifically, Sushko teaches that the device is to treat urinary diseases (see page 2, lines 45-50, and 88-93.) However, Sushko does not teach the dimensions of the suppository as claimed in claims 16, 17, 24, 25, 30, 31, 51, 52, 57, 59, 60 and 73-75.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In this case, Sushko teaches the general conditions of the claims, and discovering the dimensions as would be necessary to fit inside the body of patients is a discovery of optimum or workable ranges and thus involves only routine skill in the art under *In re Aller*.

As to claims 61 and 64, Sushko also does not teach that the base member is not for insertion into the urethra. However, Sushko teaches using the suppository in a female posterior or anterior urethra (page 2, lines 89-92) and that flaps (13 and 14) (i.e., the base member) can be folded backwardly to adhere to the flesh so as to further secure the bougie in position. It would have been obvious to one of ordinary skill in the

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art at the time the invention was made to secure the bougie using members 14 and 15 such that it does not insert into the urethra as necessary to deliver medicament in the posterior or anterior urethra because Sushko teaches the general use of the adhesives on members 14 and 15 to retain the device and that the device can be used for treatment in the various parts of the body.

As to claims 76 and 79, Sushko does not specifically teach that a segment of the reinforcement remains in the urethra and another segment remains in the bladder. However, Sushko teaches that the device can be used for delivering medicine in the bladder (page 2, lines 45-50) and urethra (page 2, lines 88-92) when the device is in these regions. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Sushko suppository such that a segment remains in the bladder and a segment remains in the urethra as necessary to treat affected regions because Sushko teaches that the bladder and urethra may be treated with medicament when the device is within these affected regions.

As to claims 62, 63, 77 and 78, Sushko also does not teach maintaining the suppository for the duration of time as claimed by Applicant for delivery of medicine. However, discovering the optimum or workable range of time for delivering medicine requires only routine skill in the art under *In re Aller*.

5. Claims 22 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sushko, 1,767,785, in view of Jackson et al., 4,542,020.

Sushko discloses the invention substantially as claimed (see above), except for the mettable portion comprising cellulose.

Jackson also teaches a suppository that melts for delivery of medication (column 62-65.) The suppository melts when placed in the patient (column 3, lines 24-28.) Jackson further teaches that the suppository comprises cellulose (column 3, lines 5-10) in order to provide for uniform distribution of the medication (col. 2, lines 6-12.)

It would have been obvious to provide cellulose in the mettable portion of the Sushko suppository in order to provide the advantage of uniform distribution of medication as taught by Jackson.

6. Claims 23 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sushko, 1,767,785, in view of Sameshima et al., 6,270,789.

Sushko discloses the invention substantially as claimed (see above), except for the medicament comprising antibiotics. However, Sameshima et al. disclose that a urethral suppository may contain antibiotics as a the medicament (col. 1, lines 16-20 and col. 2, lines 38-42.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide antibiotics as taught by Sameshima et al. as the medicament generally disclosed by Sushko because Sameshima et al. teach that urethral suppositories may contain antibiotics, as would be desired for treating infections.

***Response to Arguments***

Applicant's arguments with respect to the above rejected claims but are moot in view of the new grounds of rejection.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L. 

  
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11/28/05